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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/554,182

07/17/2006

Dugal Simon Stewart James

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06/10/2008

OHLANDT, GREELEY, RUGGIERO & PERLE, LLP
ONE LANDMARK SQUARE, 10TH FLOOR
STAMFORD, CT 06901

EXAMINER

SIGLER, JAY R

ART UNIT

PAPER NUMBER

3733

MAIL DATE

DELIVERY MODE

06/10/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/554,182

Applicant(s)JAMES, DUGAL SIMON
STEWART**Examiner**

JAY R. SIGLER

Art Unit

3733

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 April 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5 and 12-25 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5 and 12-25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 21 October 2005 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>21 October 2005</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group I, species A, and species Y, directed to claims 1-5 and 12-15 in the reply filed on 16 April 2008 is acknowledged. Firstly, the traversal is on the ground(s) that there would not be a serious burden. This is not found persuasive because the application is a national stage entry of an international application and therefore the restriction was based on the unity of invention requirement. Determining a lack of unity of invention does not require showing a serious burden; see MPEP 1893.03(d). Secondly, the examiner did not mean to require restriction between species A and species Y. A first restriction was between species A and species B. A second restriction was between species X and species Y. Therefore, the examination will include species A and species Y.

The requirement is still deemed proper and is therefore made FINAL.

Priority

2. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

3. The disclosure of the prior-filed application 2003901971 in Australia, fails to provide adequate support or enablement in the manner provided by the first paragraph of 35 U.S.C. 112 for one or more claims of this application. A screw thread being on the head of the shaft (see claims 1-5, 12-15, and 20-22) is not supported in the disclosure of the prior-filed application. Therefore, the date of the international application, 23 April 2004, will be used as the date of invention concerning claims 1-5, 12-15, and 20-22.

Drawings

4. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the "lock nut" of claim 2 must be shown or the feature(s) canceled from the claim(s). Claims 1 and 2 are considered to be drawn to the embodiments of Fig. 9-13b which do not show a lock nut that has an internal thread corresponding to the first external screw thread of the head of the shaft. **No new matter should be entered.**

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 1-5 and 12-15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

7. Claim 1, line 14-19 is considered unclear because of the language "wherein the first and second screw portions **each have an external screw thread**..., and **said external screw thread** configured..." (emphasis added). The language "each" is considered to provide an external screw thread of the first portion and an external screw thread of the second portion. Therefore, it is unclear which external screw thread "said external screw thread" is referring too. The following language is suggested: --and the external screw thread of the first screw portion and the external screw thread of the second screw portion are configured--.

8. In claim 2, line 2-5, "further comprising a lock nut having a second internal screw thread corresponding with said first external screw thread, and configured to maintain the position of said second screw portion on said shaft" is misdescriptive. Firstly, claims 1 and 2 are considered to be drawn to the embodiments of Fig. 9-13b which do not show a lock nut. Secondly, the lock nut, seen in the other embodiments, engages a thread at the opposite end of the shaft from the head. The examiner considers there to be a great deal of confusion and uncertainty as to the proper interpretation of the

limitations of claim 2, and therefore, it would not be proper to reject claim 2 on the basis of prior art.

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claims 16-19, 23, and 24 are rejected under 35 U.S.C. 102(b) as being anticipated by Bramlet (5,827,285, cited by applicant). Bramlet teaches

a. Concerning claim 16, 17, and 19, a longitudinal shaft having a head and a longitudinal axis; a first screw portion rotatable about said longitudinal axis; a second screw portion rotatable about said longitudinal axis independently of said first screw portion, wherein said first and second screw portions each have an external screw thread having a first thread direction and configured to engage a bore formed in the first and second members (see Fig. 2 in Bramlet and modified Fig. 7 below).

b. Concerning claim 18, 23, and 24, element 250 can be considered a lock nut; the shaft would be at least flexible to a small degree; first and second members are bone (see Fig. 2);

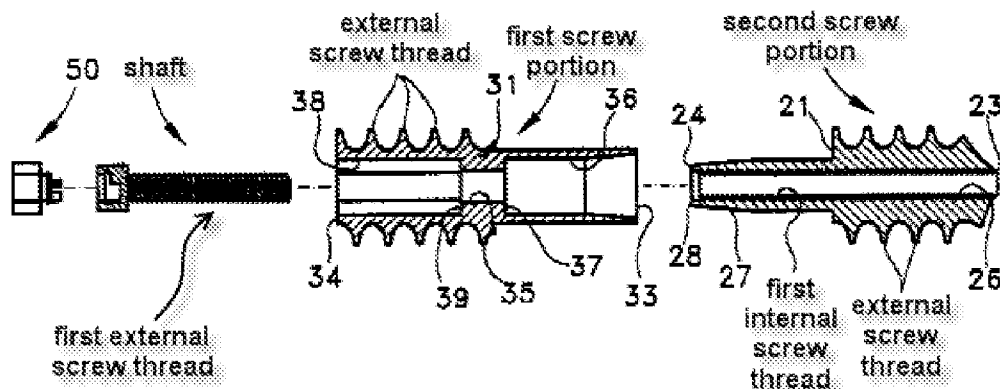


FIG. 7

Claim Rejections - 35 USC § 103

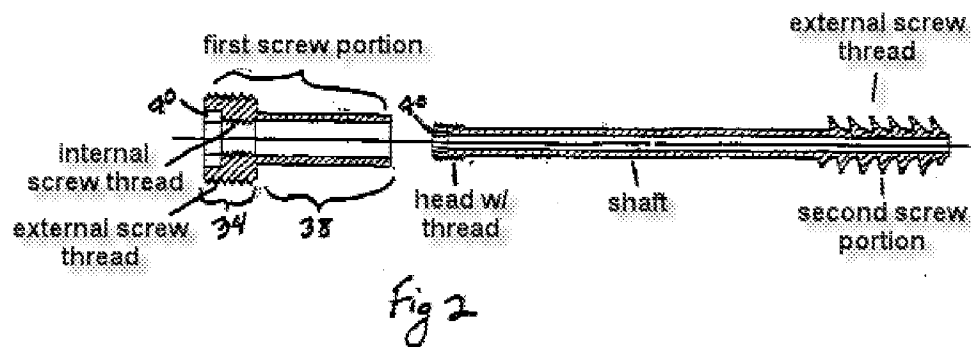
11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

12. Claims 1, 3-5, 12, 13, 15, 16, and 20-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kyle (US 2005/0143735) in view of Asnis et al. (US 5,498,265, cited by applicant). Concerning prior art references, claims 1-5, 12-15, and 20-22 are considered as having a date of invention of 23 April 2004. The claims are unpatentable for the following reasons:

c. Concerning claims 1, 15, 16, and 20, Kyle teaches a shaft having a head and a longitudinal axis; a first external screw thread on said head; a first screw portion; a first internal screw thread on said first screw portion for engaging said first external screw thread; and a second screw portion; wherein the first and

second screw portions each have an external screw thread (see modified Fig. 2 below), but not specifically that the screw thread on the head is in a different direction then the external thread on the screw portions. Asnis et al. teaches a having a different direction thread on a head portion 24 then on a second screw portion 26 in order to allow a first screw portion 52 to be used both as a insertion means and a compression means for the implant (see col. 6, l. 34-53). It would have been obvious to someone of ordinary skill in the art at the time of the invention to have different direction screw threads on in the invention of Kyle, in view of Asnis et al., in order to allow the first screw portion to be used both as an insertion means and a compression means for the implant. The method claim would naturally follow using the device as shown in Fig. 6 and 7 and described in ¶ 19.



d. Concerning claim 3-5, 12, 13, 21, 22, the threads can have a flat end (see ¶ 21; embodied by a closed end); the screw portion is integral with the shaft; the shaft would at least be flexible to a small degree; the first and second member are bone (see Fig. 6 and 7)

13. Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kyle (US 2005/0143735) in view of Asnis et al. (US 5,498,265) as applied to claim 1 above, and further in view of Challenger, Jr. (US 3,996,931).

e. Kyle, in view of Asnis, suggests the claimed invention, but not specifically the retaining screw. Challenger, Jr. teaches a retaining screw 32 in order to retain a second member 28 in a first member 26. It would have been obvious to someone of ordinary skill in the art at the time of the invention to include a retaining screw in the combination of Kyle and Asnis, in view of Challenger, Jr., in order to better retain the second screw portion in the first screw portion.

14. Claim 25 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bramlet (5,827,285) as applied to claim 16 above, and further in view of Challenger, Jr. (US 3,996,931).

f. Bramlet teaches the claimed invention, but not specifically the retaining screw. Challenger, Jr. teaches a retaining screw 32 in order to retain a second member 28 in a first member 26. It would have been obvious to someone of ordinary skill in the art at the time of the invention to include a retaining screw in the invention of Bramlet, in view of Challenger, Jr., in order to better retain the second screw portion in the first screw portion.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JAY R. SIGLER whose telephone number is (571)270-3647. The examiner can normally be reached on Monday through Thursday from 8 AM to 4 PM (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on (571) 272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/J. R. S./
Examiner, Art Unit 3733
/Eduardo C. Robert/

Supervisory Patent Examiner, Art Unit 3733